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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/532,396	03/22/2000	Youmin Wang	6207.N CN1	8049

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/532,396	WANG ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

The request filed on November 4, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/532,396 is acceptable and a CPA has been established. An action on the CPA follows.

The amendments filed September 9, 2002 have been entered.

The addition of claims 24-26 is acknowledged.

Claims 1-26 are pending.

Claim Objections

Claims 22, 23, and 26 are objected to because of the following informalities: the use of abbreviations in claim 22: "GDO/GMO", in claim 23: "GDO", "MCT/GDO", in claim 26: "GDO/GMO" is considered improper. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romines et al., (USPN 5,852,195) and Suzuki et al. (USPN 5,693,337) in view of Remington (Remington's Pharmaceutical Sciences, 18th ed., page 1172, 1286, 1316 and 1317) and Lyons (US Patent 5,616,342).

Romines et al., (USPN 5,852,195) teaches the pyranone compound of formula I recited in claim 1 of the instant application. Romines et al., (USPN 5,852,195) also teaches that the pyranone compound can be administered orally and parenteraly. Romines et al., (USPN 5,852,195) further teaches that also parenteral suspensions of the pyranone composition can be prepared. See claims, more specifically claim 3, as well as col. 47 lines 61-65 and col.48 lines 21-47.

Romines et al., (USPN 5,852,195) does not teach the incorporation of pyranone in an emulsion. Consequently neither does it teach the employment of lecithin, an oil component, a liquid phase or weight percentages of each of the said components.

Suzuki et al. (USPN 5,693,337) teaches a stable lipid emulsion comprising water, an oil component and yolk and/or soy bean lecithin, see abstract. Furthermore Suzuki et al. (USPN 5,693,337) teaches that similar effects are expected from dimyristoylphosphatidylcholine and dipalmitoylphosphatidylcholine and are used with yolk lecithin and/or soybean lecithin, col. 3, lines 1-12. Suzuki et al. (USPN 5,693,337) teaches the amount of emulsyifying agents (i.e., lecithin) to be from 1/50 to 3 parts by weight, col. 3, lines 13-17. Moreover the oil component in Suzuki et al. (USPN

5,693,337) include mono-, di- or triglycerides whose acid components are C6-C20 saturated and/or unsaturated fatty acids and mixtures comprising at lease two members of these glycerides. The amount of these oil components is not particularly restricted, but preferably ranges from 0.1 to 50%, col. 4, lines 54-67. Finally, Suzuki et al. (USPN 5,693,337) teaches that many different types of drugs including antiviral drugs can be added to the lipid emulsion, see col. 5 and col.6.

Romines et al., (USPN 5,852,195) and Suzuki et al. (USPN 5,693,337), taken together, do not teach the particular ratios of the mixture of mono-, di- and triglycerides. Moreover they do not particularly teach the weight ratio of the pyranone compound of formula I in the emulsion. They do not expressly teach the various excipients recited herein, such as BHT, methyl paraben, propylparaben, sodium deoxycholate, propylene glycol, and glycerine.

Remington teaches the BHT is an antioxidant, methylparaben are useful with propyl paraben as preservatives, glycerine and propylene glycol are well-known pharmaceutically acceptable solvents.

Lyons teaches that deoxycholate, which is a bile salt, can be used as a co-surfactant in an emulsion (See the abstract; and claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the anti-retroviral composition of Romines et al., (USPN 5,852,195) in the lipid emulsion taught by Suzuki et al. (USPN 5,693,337). It would have further been obvious to optimize the amounts of the pyranone compound and the sub-components of the oil component of the Suzuki et al.'s emulsion.

One of ordinary skill in the art would have been motivated to incorporate the antiretroviral pyranone compound in a stable lipid emulsion such as that of Suzuki et al. (USPN 5,693,337) for its storage stability as well as potentially increased solubility. Moreover optimization of amounts is within the purview of the skilled artisan. Incorporating the herein claimed well-known excipients into the composition would be considered obvious as being within the purview of the skilled artisan, absent evidence to the contrary.

Response to Arguments

Applicant's arguments filed September 9, 2002 averring the cited prior art fails to teach the particular mixture of mono-, di- and triglyceride or the amount of the active compound have been fully considered but they are not persuasive. The use of mono-, di- or triglycerides was taught by Suzuki et al. The active compounds was taught by Romines et al. The optimization of specific amount of each of the components employed would be considered obvious to one of ordinary skill in the art, absent showing the criticality of the specific ratio of the mono, di- or triglycerides employed herein.

Applicant argues that Suzuki et al. requires the presence of citric acid in its emulsion. Note that the instant claims contain the open transitional phrase "comprising" which does not exclude the presence of other components, e.g., citric acid. Applicant also argues the manner in which the components in Suzuki are being mixed is unclear and he further explains the method of preparation of the instant pharmaceutical

composition. Note that none of the instant claims are drawn to method of making and/or mixing. Arguments as to unclaimed limitations are moot.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
January 23, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

1/25/03